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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,019	06/26/2003	Richard K. Cooper	51687-0101 (287015)	8431
23370	7590	11/07/2006	EXAMINER SINGH, ANOOP KUMAR	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			ART UNIT 1632	

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/609,019

Applicant(s)

COOPER ET AL.

Examiner

Anoop Singh

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 52-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 52-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/10/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on September 26, 2006, has been received and entered. Claims 22-51 have been canceled, while claims 73-80 have been added. Applicants have also amended claims 1-4, 20-21, 52-54, 57-65, 67-72. Claims 1-21, 52-72 and newly added claims 73-80 are under consideration in the instant application.

Election/Restrictions

Applicants election on telephone and reaffirmation of the telephonic election with traverse of the invention of group I (Claims 1-21) was acknowledged.

Declaration

The declaration filed on September 26, 2006 under 37 CFR 1.132 is considered but is not sufficient to overcome the rejection of claims 1-21 and 52-80 as it applies to the rejection in this office action.

Claim Objections

Claim 1, 52 and 63 are objected to because of the following informalities: In the instant case, claims do not recite the limitation in right syntax. For instance recitation of claims 1 step (a), 52 step (a) and 63 step (a) as "...encod[ed]ing the modified codon" will overcome this objection. Appropriate correction is required.

New-Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21, 52-72 and newly added claims 73-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118(a) states "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". In the instant case, the recitation of limitation... "plurality of the first ten codons of the transposase gene are individually modified from the wild type sequence at the third base position of the codon .." (claims 1, 52 and 63) and each of 2-10 codon of the "...modified transposase gene" (claims 52 and 63) are considered new matter. Applicants point to page 58 for the specific support of the claimed amendment of a transposase gene that is modified such that a plurality of first ten codon of the transposase gene are individually modified from the wild type sequence. However, upon further review of the instant specification, examiner could only find support for codons for the first ten amino acids of the transposase gene wherein G or C is changed to A or T without altering the amino acid encoded by the modified transposase (see page 58). Since as amended claims require one or all the first ten codons to be individually modified which is not optional rather it is required to be an A or T at third base position of first ten codons. It is emphasized that specification provides support directly to codons for the first ten amino acid of the transposase and not to the plurality of first ten codons (30 amino acids) as contemplated by the amended claims. In addition, limitations of claims 1, 52 and 63 also do not have any explicit support in the specification. It is noted that this section does not provide the specific conditions, nor what and how one determines an equivalent that would generically apply to the claimed invention.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph-written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981) teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time application was filed... If a claim is amended to include subject matter, limitation or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes, "When an amendment is filed in reply to an objection or rejection based on U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendment made to the disclosure".

To the extent the claimed modified transposase genes are not described in the instant disclosure, claims 1-21, 52-72 and newly added claims 73-80 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since the applicants disclosure do not teach a transposase gene that is modified such that plurality of first ten codons of the transposase gene are individually modified from wild type sequence to an adenine to thymine at the third base position of the codon. In this case, it appears that the claims reflect modifying one or all of first ten codons at third base position of each of the codon, not for codons for first ten amino acid as described in the specification. In addition, as recited modification of one or all the ten codons appears not an option rather it is required without changing the amino acid encoding the modified transposase. It is noted that the first codon ATG of the wild type transposase a changed to changed to ATT or ATA would make the transposase non functional. As described before, the specification does not provide adequate guidance on determining what is included or excluded by the claims as amended and therefore an

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artisan of skill would require undue experimentation to practice or make and/or use the invention.

New -Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21, 52-72 and newly added claims 73-80 are rejected under 35 U.S.C. 112, first paragraph and newly added claims 45-49 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In determining whether Applicant's claims are enabled, it must be found that one of skill in the art at the time of invention by applicant would not have had to perform "undue experimentation" to make and/or use the invention claimed. Such a determination is not a simple factual consideration, but is a conclusion reached by weighing at least eight factors as set forth in In re Wands, 858 F.2d at 737, 8 USPQ 1400, 2d at 1404. Such factors are: (1) The breadth of the claims; (2) The nature of the invention; (3) The state of the art; (4) The level of one of ordinary skill in the art; (5) The level of predictability in the art; (6) The amount of direction and guidance provided by Applicant; (7) The existence of working examples; and (8) The quantity of experimentation needed to make and/or use the invention.

The office has analyzed the specification in direct accordance to the factors outlines in *In re Wands*. MPEP 2164.04 states: "[W]hile the analysis and conclusion of a lack of enablement are based on factors discussed in MPEP 2164.01(a) and the

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evidence as whole, it is not necessary to discuss each factor in written enablement rejection." These factors were analyzed, in turn, to demonstrate that one of ordinary skill in the art would have had to perform "undue experimentation" to make and/or use the invention and therefore, applicant's claims are not enabled.

Claims 1-21, 52-72 and newly added claims 73-80 are broad in scope. The following paragraph will outline the full scope of the claims.

These claims are broad in scope, encompassing a vector comprising a nucleic acid sequence comprising a prokaryotic transposase gene that is modified such that a plurality of the first ten codons of the transposase gene are individually modified from the wild type sequence at the third base position of the codon to an adenine or thymine at the third base position of the codon. As amended instant claims require modification in one or all ten codons of the transposase gene. The specification has taught that the claimed invention features a base pair 1783-2987 of SEQ ID NO: 1 are the coding sequence for the transposase modified from Tn10 by optimizing codons for stability of the transposase mRNA and the expression of the protein. The specification has exemplified that each of the codons for first ten amino acids of the transposase G or C is changed to A or T without altering the amino acid encoding the modified codons (see page 58, fifth paragraph). Prior to instant invention, Schulz et al (J. Mol. Biol., 1991, 221: 65-80; art of record) taught a Tn5 gene sequence having codons with an A or T in the third position (see figure 2 on page 69 in particular see the codons immediately upstream or downstream of the AUG codon). However, it does not provide any guidance and rational to modify first ten codons of the transposase gene. In the instant case, first ten codons of base pair 1783-2987 of SEQ ID NO: 1 are ATG TGT GAA CTT GAT ATT TTA CAT GAT TCT. In the instant case, claims require any of one or all the first ten codons to be modified by an A or T at the third base position of the each codon, which is not an option rather such a change is required by the claims without changing amino acid encoding the modified transposase. However, it is noted that changing third base of first codon from ATG to adenine or thymine would change the start codon methionine to isoleucine. In addition, instant claims comprise a promoter comprising a Kozak sequence as set forth in SEQ ID NO: 13 (ACC ATG) that is positioned to include

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at least first codon of the transposase gene. It is not apparent if first codon of transposase gene is changed at third base to include A or T would change the Kozak sequence as described in instant application. Therefore, it would appear in the absence of evidence to the contrary that the instant specification has not taught a promoter comprising a Kozak sequence that includes a transposase gene that is modified at the third base position of each of the first ten codons of the transposase gene.

Given the lack of guidance provided by the specification it would have required undue experimentation to make and use a modified transposase gene for one of skill in the art without a reasonable expectation of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21, 52-72 and newly added claims 73-80 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-21, 52-72 and newly added claims 73-80 are vague and indefinite to the extent that they recite a promoter that comprises Kozak sequence ACC ATG being positioned so as to include at least first codon of the transposase gene wherein transposase gene is modified such that plurality of first ten codons of the transposase gene that is modified to include A or T at the third base. As recited instant claims also embrace any and all of the first ten codon of the transposase gene and modifying G of third base of ATG from the first codon to A or T would essential alter the Kozak sequence as well as the amino acid encoded by the modified codon. The meets and bound of the claims are not clear. In addition, it is also noted that claims 52 and 63 recite the same limitation as discussed above and also recite the limitation wherein modified transposase gene comprises an A or T at the third position in each of codon 2-10. This is contradictory to other limitation in the claims that describes plurality of first

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ten codons are modified to include A or T at third base without altering amino acid. It is emphasized that this limitation also embraces the first codon ATG, which is also contemplated to be changed at third base position. The meets and bounds of the claims are not clear. Claims 2-21, 43-62, and 64-80 are directly or indirectly depends on claims 1, 52 and 63. Appropriate correction is required.

Withdrawn-Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-10 and 15-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Cooper R. (US 5,719,055), Meiss et al (Bio techniques, 2000, 29(3): 476, 478, and 480) taken with Fischer et al (PNAS, 2001, 98 (12), 6759-6764) is withdrawn in view of amendment to the claim 1. It is noted that instant rejection was based on recitation that transposase gene comprises at least one of the first twenty codon of the transposase gene is modified by changing a nucleotide at a third base position of the codon to an adenine or thymine without modifying the amino acid encoded by the codon. As amended claims now recite plurality of first ten codon of the transposase gene are individually modified from the wild types sequence at the third base position of the codon to an adenine or thymine at the third base position of the codon. Applicants arguments are persuasive that there is no specific motivation in any of the cited reference to change one or all the ten codon as recited in amended claims, therefore rejection for claims 1-6, 8-10 and 15-17 is withdrawn.

Claims 1-11, 15-20, 52-53, 57-62 rejected under 35 U.S.C. 103(a) as being unpatentable over Cooper R. (US 5,719,055), Meiss et al (Biotechniques, 2000, 29(3):

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476, 478, and 480), Fischer et al (PNAS, 2001, 98 (12), 6759-6764) and further in view of Hackett et al (US Patent no. 6489458, dated 12/3/2002, filing date 9/10/1998) is withdrawn in view of the amendments in independent claims 1 and 52 for the same reasons as discussed above.

Claims 1-20, 52-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooper R. (US 5,719,055), Meiss et al (Biotechniques, 2000, 29(3): 476, 478, and 480), Fischer et al (PNAS, 2001, 98 (12), 6759-6764), Hackett et al (US Patent no. 6489458, dated 12/3/2002, filing date 9/10/1998) and further in view of Wallace, R. A, King J.L and Sanders, G.P., (Biology: The Science of Life, 1986, Scott Foresman and Company, pp 235) is withdrawn in view of the amendments in claims 1 and 52 for the same reasons as discussed above.

Conclusion

No claims allowed.

The following art made of record and not relied upon is considered pertinent to applicant's disclosure:

Koga et al (J Human Genet, 2003, 48: 231-235, published online 3/28/2003) teach pHe103 plasmid (figure 1) tyrosinase gene, Tol2 transposase and translation start and stop codon in helper plasmid pHe103. It is noted that nucleic acid sequence 3' to the CMV promoter comprises the Kozak sequence (ACCATG), the Kozak sequence being positioned to include the first codon of the Tol2 transposase. Koga et al is not applied as prior art due to earlier priority date of instant application.

Cooper R. (US 5,719,055)

Meiss et al (Bio techniques, 2000, 29(3): 476, 478, and 480)

Fischer et al (PNAS, 2001, 98 (12), 6759-6764)

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

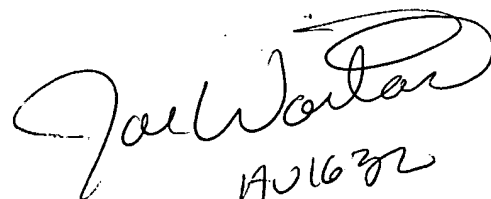
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272- 0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anoop Singh, Ph.D.
AU 1632



Handwritten signature of Anoop Singh, with the text "AU 1632" written below it.